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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,651

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Maik Kindermann

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,651	<b>Applicant(s)</b> KINDERMANN ET AL.	
	<b>Examiner</b> /Mark L. Berch/	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4,5-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 2,4,5,8-25,27,28 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2008 has been entered.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 5, 8-25, 27-28, 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The definition of label in claim 2 remains unclear. Note that L is a moiety, but a lipid is a molecule.
2. The claim 2 provision for a plurality of labels is unclear. The formula shows only one L. If R4 can have several L groups attached, then the formula must be amended accordingly. Or is the second L attached to the first L? Note in this regard that R4 is an

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alkylene group, which has exactly two bonds, one of which must be used to attached to R3.

3. It is unclear where the list of labels in claim 2 ends. This is important because there can be a plurality of labels, but things that are not labels, there cannot be a plurality of these.
4. At next to last line of claim 2, what does "moiety with membrane-inserting properties" mean? Is this something which inserts a membrane into something, in which case, into what? Is it something which attaches itself to a membrane, i.e. inserts itself onto a membrane? Is it something which passes through? And in any case, what sort of membrane? Is this a cell membrane, or would it cover organ membranes such as a mucous membrane, or would it cover artificial membranes such as Polymeric membranes?
5. The wording "a moiety which is one part of a specific binding pair selected from biotin...." is unclear. What part would that be? For example, Streptavidin is a protein, which means that it has e.g. guanine present as a part, so does this read on guanine? Avidin has a urea group, so with this cover a urea group? Note that the claim uses "comprising", meaning that its just part. Thus, any compounds which has a urea functionality anywhere present would be "comprising" the urea group. Another "part" of avidin is a tetramethylene group. Does that mean that any compound with a tetramethylene is embraced?
6. It is also unclear whether claim 28 requires that all of the reactive groups be protected, or just two or more. Only two Deprotection steps are required, and the clm does not state that all are protected.

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7. Related to this is the problem of groups which cannot be protected. Electrophilic groups, such as halogen or nitro cannot be protected. Does this mean that claim 28 simply does not include such groups? Or does it mean that these groups can be present, so long as there are at least two protecting groups around to be deprotected? There's no way of telling.
8. Claim 31 is very unclear. It is unknown what "manipulating" is supposed to cover. The traverse is unpersuasive. Applicants point to description of the fusion protein, but that does not tell us what "manipulating a protein of interest means". Applicants further points "in particular page 14, lines 1-26, for "manipulating" as binding to a solid support and further steps made possible by binding to a solid support". But there is no indication there that "manipulating" means binding to a solid support. It simply says that the fusion protein can be bound to a solid support. Further, it is hard to see how it will fit. All that claim 31 actually requires, for the manipulating branch of the claim, is contacting the fusion protein "with an AGT substrate carrying a label". That doesn't seem to have anything to do with binding to a solid support. Moreover, even if true what else would "manipulating" cover other than this? Applicants also point to the next paragraph, but that deals with studying the role of the proteins, and detecting the proteins, which does not tell us the scope of manipulating the proteins. That is manipulating the proteins doesn't necessarily entail studying them.
9. The term "polyfunctional residue" in claim 27 is unclear. Residue of what? It is understood that there are attached two or more reactive groups, but these are attached to what? Could this R<sub>4</sub>' be e.g. dichlorophenyl?

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10. Claim 28 now has the new language “extending the polyfunctional residue R<sub>4</sub>”. What does this mean? Adding more reactive groups? Converting carbon-carbon double bonds into single bonds (which are longer than double bonds)? Adding more atoms to the backbones?
11. The relationship between claim 27 and claim 28 is very unclear. The moiety R<sub>4</sub>' is in the starting material. In claim 27, one reacts this starting material with “a suitable reagent introducing one or more labels L” and one gets a compound of Formula I, which of course does not have R<sub>4</sub>' but instead has R<sub>4</sub>-L. Therefore, claim 28 cannot be a further step after what happens in claim 27. However, claim 28 says, “comprising the further steps of...”
12. Related to this is the ambiguous wording of “...groups in R<sub>4</sub>' are protected by....” Is this an actual step, i.e. a protection step? Or is it merely a description of the structure of R<sub>4</sub>'? The claim can be read either way.
13. Further, if the latter is true, then the claim seems to conflict with claim 27, which says that it has “reactive nucleophilic or electrophilic groups”. It says nothing about the groups being protected --- and protecting is done to prevent things from being reactive.
14. What does “depending on the number of” mean in step (c) of claim 28. Does this mean that you do it as long as there are any groups left to deprotect?
15. R<sub>4</sub>, choice (b) is unclear. The material before “representing” would appear to cover both NHCO and CONH, but the claim goes on to give only the former. Is only the former intended? In addition, the “or more” would appear to permit NHNHCO as well as NHCONH, but again, these do not appear after the “represents”. Are these included?

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16. L=methotrexate is not correct, since methotrexate is a molecule. It is also not entirely clear what in the amended L definition now in claim 2 would provide for this.

Claims 2, 4, 5, 8-17, 19-22, 24-25, 27-28, 31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A. Claim 28 now has the new language "extending the polyfunctional residue R<sub>4</sub>". Where is this in the specification?

B. Where is this process of claim 28 described in the specification? For example, the original claim 28 had the extension of R<sub>4</sub>, but the claim now has the extension of R<sub>4</sub>'.

C. Note point 5 above. There is no evidence that applicants ever intended any such scope for L.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

12/31/2008